

Serial No. 10/505,355
Response Dated April 18, 2008
Response to Restriction Requirement dated March 27, 2008

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (withdrawn) A therapeutic composition for symptomatic treatment of respiratory allergies in a warm-blooded animal, said composition comprising a pharmaceutically effective amount of diphenhydramine tannate of consistent purity in substantial absence of an organic solvent.
2. (withdrawn) The composition of claim 1, wherein said organic solvent is an alcohol.
3. (withdrawn) The composition of claim 1, wherein said organic solvent is a mineral oil.
4. (withdrawn) The composition of claim 1, wherein said organic solvent is isopropyl alcohol.
5. (withdrawn) The composition of claim 1, wherein said organic solvent is glycerin.
6. (withdrawn) The composition of claim 1, wherein said organic solvent is propylene glycol.
7. (withdrawn) The composition of claim 1, wherein said organic solvent is ethanol.

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8. (withdrawn) The composition of claim 1, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.

9. (withdrawn) A therapeutic composition for symptomatic treatment of respiratory allergies in a warm-blooded animal, said composition comprising a pharmaceutically effective amount of diphenhydramine tannate of consistent purity in substantial absence of decomposition products of diphenhydramine produced at temperatures above about 50 degrees C.

10. (withdrawn) The composition of claim 9 wherein said decomposition product is benzhydrol.

11. (withdrawn) The composition of claim 9 wherein said decomposition product is benzophenone.

12. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenylchloromethane.

13. (withdrawn) The composition of claim 9 wherein said decomposition product is dimethylaminoethanol.

14. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenylmethane.

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15. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenyl alkyl ether.

16. (withdrawn) The composition of claim 9, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.

17. (original) A therapeutic composition for symptomatic treatment of respiratory allergies in a warm-blooded animal, comprising a pharmaceutically effective amount of diphenhydramine tannate of consistent purity prepared in a preferred way by:

(a) dissolving the salt or free base of the diphenhydramine in a pharmaceutically acceptable liquid to form a solution at a maximum temperature and pH value, that does not cause decomposition of the active pharmaceutical ingredient;

(b) separately adding a dispersing agent and tannic acid to a pharmaceutically acceptable liquid, under stirring, to form a dispersion;

(c) transferring the solution from step (a), in portions to the dispersion in step (b) under stirring, to form a precipitate of a tannate salt of diphenhydramine; and

(d) combining the tannate salt of the diphenhydramine without isolation or purification with pharmaceutically acceptable excipients to generate a therapeutic dosage form.

18. (original) The composition of claim 17, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.

19. (withdrawn) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate of consistent purity in substantial absence of an organic solvent.

20. (withdrawn) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate of consistent purity in substantial absence of decomposition products of diphenhydramine produced at temperatures above about 50 degrees C.

21. (original) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate of consistent purity prepared in a preferred way by:

(a) dissolving the salt or free base of the diphenhydramine in a pharmaceutically acceptable liquid to form a solution at a maximum temperature and pH value, that does not cause decomposition of the active pharmaceutical ingredient;

(b) separately adding a dispersing agent and tannic acid to a pharmaceutically acceptable liquid, under stirring, to form a dispersion;

(c) transferring the solution from step (a), in portions to the dispersion in step (b) under stirring, to form a precipitate of a tannate salt of diphenhydramine; and

(d) combining the tannate salt of the diphenhydramine without isolation or purification with pharmaceutically acceptable excipients to generate a therapeutic dosage form.

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22. (withdrawn) The composition of claim 1 in substantial absence of any other active ingredient.

23. (withdrawn) The composition of claim 1 in substantial absence of any other tannate salt.

24. (withdrawn) The composition of claim 9 in substantial absence of any other active ingredient.

25. (withdrawn) The composition of claim 9 in substantial absence of any other tannate salt.

26. (original) The composition of claim 17 in substantial absence of any other active ingredient.

27. (original) The composition of claim 17 in substantial absence of any other tannate salt.